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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,001

07/19/2004

Nisar P Malek

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6809

7590

08/22/2007

Brian W Poor  
Townsend and Townsend and Crew  
Two Embarcadero center  
8th Floor  
San francisco, CA 94111

EXAMINER •

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

08/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/502,001

Applicant(s)

MALEK ET AL.

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6,7 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on N/A is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/06/2007 has been entered.

Claims 1,6 and 7 have been amended. Claims 4,5 and 8-37 have been cancelled. Claim 38 has been added. Claims 1-3,6,7 and 38 are pending and under consideration in the instant office action.

### *Claim Objections*

Claim 6 is objected to because of the following informalities: Claim 6 depends from claim 39. There is no claim numbered 39. As such, claim 6 is interpreted as though it depends from claim 38. . Appropriate correction is required.

This application contains claims 6,7 and 38, which encompasses an invention nonelected with traverse in the election dated 05/15/2006. A complete reply to the final rejection must include removal of nonelected subject matter from the claims or other appropriate action (37 CFR 1.144).

Claim 38 is being examined as it reads on the elected invention wherein the mutant p27 gene is located at the endogenous p27 locus, resulting in a loss of endogenous, wildtype p27. It is also noted that the claim fails to recite the term "isolated", thus the claim reads on a cell *in vivo*, which is a murine animal, which is non-elected subject matter. If claim 38 is amended to read on the elected invention, claims 6 and 7 will be of the same scope as claim 38.

***Claim Rejections - 35 USC § 112-1st paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-7 remain rejected and newly added claim 38 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) an isolated transgenic somatic cell or ES cell or 2) an isolated transgenic mouse primordial germ cell, oocyte, egg, spermatocyte, sperm cell, fertilized egg, zygote, each having a mutant p27 gene lacking a Cdk2 phosphorylation site located at the endogenous p27<sup>Kip1</sup> locus, wherein the mutant p27 gene encodes a mutant p27<sup>Kip1</sup> polypeptide having a longer half-life in S phase than wildtype p27<sup>Kip1</sup> polypeptide, does not reasonably provide enablement for a non-mouse primordial germ cell, oocyte, egg, spermatocyte, sperm cell, fertilized egg, or zygote as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The rejection is withdrawn as it relates to claims 1-3, which are now limited to somatic and ES cells that can be made in vitro and do not require an embryo or animal for their isolation.

The rejection is maintained as it relates to claims 6,7 and 38 for reasons of record set forth at pages 3-6 of the office action dated 06/21/2006. While Applicant has amended the claims to limit them to murine species, murine species includes species of animal other than mouse, including rat (see <http://encarta.msn.com/encnet/features/dictionary/DictionaryResults.aspx?refid=1861631945>, printout attached).

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is rendered moot by the cancellation of the claim.

The following new rejection is necessitated by amendment.

Claims 1-3,6,7 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 38 are unclear. They recite that the cell has a mutant endogenous p27 gene. It is not clear if Applicant intends to encompass a naturally occurring mutation at the endogenous p27 gene, which is what one of skill in the art would interpret by the use of the term “endogenous”. This is not what is taught by the specification. The specification teaches replacement of the endogenous wildtype p27 gene with an exogenous mutant p27<sup>Kip1</sup> gene. Language such as “...having a mutant p27<sup>Kip1</sup> gene lacking a Cdk2 phosphorylation site replacing the endogenous Kip1 locus such that there is a loss of endogenous, wildtype p27 activity...” would be more clear. Claims 2-3 depend from claim 1 and claims 6 and 7 are read as though they depend from claim 38 (see objection to claim 6, above).

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***Conclusion***

It is noted that Sheaff *et al* (1997) and Morimoto *et al.* (2000) each taught isolated cells comprising a mutant p27 lacking a Cdk2 phosphorylation site as encompassed by claim 1. However, the elected invention is drawn specifically to cells comprising a mutant p27 located at the endogenous p27 locus, eliminating wild-type p27. Thus, this art does not read on the elected invention and is not applied over the claims as examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio, Ph.D./  
Primary Examiner  
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